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One Size That Could Fit All: IRBs Joint Review Collaboration as the Key to Addressing the Challenges of Multinational Research Review Involving Resource-Poor Countries

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by the authors, but also to foster direct communication between investigators and IRBs while encouraging flexibility with review standards. ■

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One Size That Could Fit All: IRBs Joint Review Collaboration as the Key to Addressing the Challenges of Multinational Research Review Involving Resource-Poor Countries

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Barchi, Singleton, and Merz (2014) highlighted the main challenges arising when institutional review boards (IRBs) do ethics review of multinational research protocols and then propose a heuristic from a range of IRB collaborative mechanisms for addressing the highlighted problems. The range of the collaborative mechanisms is presented in a continuum starting from independent separate review to full joint review among the various IRBs involved in a multinational research. Barchi and colleagues have further demonstrated how these collaborative mechanisms address the specific challenges. We put forward that for a very efficient IRB review of international research involving resource-poor countries (so-called developing countries), a joint IRB should be constituted in order to review multinational research protocols. We affirm that the joint IRB is the most vital mechanism among the collaborative mechanisms and could be all that is required for an effective multinational review.

Research in resource-poor settings has been shown to present unique sets of ethical and practical challenges that are distinct from the research in industrialized countries. These challenges include but are not limited to difficulties in obtaining informed consents that are consistent with Western ethical principles, inadequate knowledge on research processes, and difficulties in distinguishing between research and clinical care delivery, as well as inadequate ethics review of research protocols and weak regulatory

oversights (Glickman et al. 2009). The inadequacies in ethics review in resource-poor settings are mostly due to shortages of both personnel and expertise of IRBs that are responsible for research protocols review. For example, an anecdotal look at the ethics committee members in Nigerian health institutions indicates that in most ethics committees there are no professional bioethicists, even though some of the ethics committee members have some form of online-based research ethics training. In many cases research sponsors in developed countries do take advantage of the weakened ethics committee in developing countries and override the IRBs ethics review from developing countries on the grounds that such reviews are professionally insufficient (Van Teijlingen and Simkhada 2012). Moreover, with the high influence on research process that sponsors have over their local host communities, local IRBs risk having little or no influence in deciding on the final outcome of ethics review even though the research is conducted in their communities. As such, in view of these challenges and the inadequacies of IRB reviews in developing countries, double independent ethical review among IRBs in multinational research involving resource poor countries may just be a mere procedural requirement due to asymmetric research influence between the North and South. This is consistent with Ravinetto and colleagues' view that double ethical review in North–South research collaboration could be criticized either as moral imperialism because it tends to

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impose standards of a specific culture onto other cultures or it as paternalistic if one considers that all countries have the capacity to enforce certain ethical standards that are unique to their population (Ravinetto et al. 2011). Similarly, Gillman and colleagues noted that IRBs in developed countries are nearly always paternalistic and have a low regard for the quality of IRB reviews in less developed countries—even though local committees know their local populations better and are more likely to protect and care for them (Gilman and Garcia 2004).

Therefore, independent ethical review does not necessarily depict a true review partnership or offer additional protection to research participants in developing countries research. To reflect a true IRB review partnership, we recommend that IRBs in a multinational research involving resource-poor countries need to collaborate and form a single special IRB where a level playing ground for adequate research review is provided. A level playing ground for adequate review should be characterized by free deliberation, sound ethical regulation, and equal interactive exchange of research expertise and cultural ideas. Wahlberg and colleagues noted this idea and suggested ways to cope with the problems associated with North–South international research collaboration (Wahlberg et al. 2013). This level playing ground will create conditions where well-balanced ethical decisions that harness different ethical and cultural viewpoints are achieved. In a semistructured interview that was meant to explore the operations of ethics committees, a Nigerian ethics committee member stated that “our review process is usually easy because the same protocols are independently reviewed in the USA prior to our review and we hardly encounter any discrepancies because these people are the experts.” This assertion gives a perception that double ethical reviews are usually one-sided, whereby IRBs in developed countries are the sole determinants of the review output in a multinational research. Joint review would dispel such perception among local IRBs and ensure that all IRBs in multinational research feel part of the research and that their voices count in ethical decision.

Albeit, it would require an additional effort in the research process, a joint IRB, if it is well coordinated, can produce a balanced joint review committee in a multinational research. In order to set up a well-coordinated joint IRB in a multinational research study, the following might be an important guide in the process: First, the research sponsor that is to conduct a research in a particular developing country needs to liaise with the national ethics governing body in that country. Many developing countries have at the national level a research ethics body that overlooks and regulate the activities as well as maintaining a register of the local IRBs in various institutions across the country—for example, the National Health Research Ethics Committee of Nigeria, National Bioethics Committee of Uganda, National Health Research Ethics Council of South Africa, and so on. Second, the national ethics governing body, based on its knowledge of the local IRBs where the research is to be conducted, can appoint a member (or members) of the local IRB to be part of the joint IRB in the multinational research.

Moreover, there have been recorded successes in joint IRBs in multisite trials within the United States; such successes can be ascertained and adapted to the formulation of joint review in multinational research, for example, the Biomedical Research Alliance of New York (BRANY) IRB (McNeil 2007). It is noteworthy to state that the joint IRB that we propose does not necessarily have to organize physical meetings where all members have to travel to a designated place. This would incur a huge logistic and financial burden on members. We are certain that with advanced technological communication networks (teleconferencing etc.) members can actively conduct successful meetings across the world. What counts in a joint IRB is not the physical meetings of members, but a unified fair procedure (devoid of paternalistic tendencies) where all views and expertise are adequately considered before decisions are taken.

Furthermore, joint review will strengthen the capacity of local IRBs in developing countries and give them confidence to conduct further reviews. There is a general call for research capacity strengthening in resource-poor countries, so that developing countries can be empowered to be self-reliant in conducting their own research. This has been shown to be a way of benefit sharing in international research (Schulz-Baldes, Vayena, and Biller-Andorno 2007). Such capacity building in health research should encompass IRBs development in resource-poor countries and this can be achieved through joint review. Also, in line with the widespread advocacy on the global justice for health and health research, the affluent countries are encouraged to uphold as an obligation and help in developing health infrastructures and research capacity in developing countries (Dauda and Dierickx 2012; Dwyer 2005). We put forward that such global justice reasoning should inculcate joint IRB review, as this will strengthen the quality of IRBs in developing countries, which in turn can contribute to the development of good ethical and legal frameworks that are tailored to the peculiarities of research in developing countries.

Hitherto, we have proposed some reasons why a joint IRB review should be preferred over the independent IRB review. The question that may ensue is whether other mechanisms in the continuum as outlined by Barchi and colleagues (open communication and the use of review consultants) are better than joint review mechanism. It is difficult to confidently assert that other mechanisms are better than or that they are as effective as the joint review mechanism because we do not have research evidence to support such claims. However, Ravinetto and colleagues expressed that in their experience in conducting research in resource-poor settings, open communications with other IRBs that independently review the same protocol are not effective and unnecessarily prolong time for review. Ethics committees usually do not proactively seek communications with other committee members with the same ethics review task and this has resulted in lack of opportunity for mutual learning among the different ethics committees (Ravinetto et al. 2011). We agree that the use of review consultants whereby review of multinational research is contracted to independent review experts can be an effective mechanism if such

consultants consist of members who have good knowledge and experiences working in developing countries (Gilman and Garcia 2004). However, a disadvantage of the use of consultants is that such independent review experts are under contract and therefore are not obliged to return benefits of review expertise to the local ethics committees after the review process. As a result, the local IRBs would miss the prospects for growth and development in their review engagements.

Our key point is that joint IRB review can go a long way in fostering true review partnership and curbing IRBs review challenges in North–South research collaboration. We recommend that more studies should be conducted in order to further establish the effectiveness, feasibility, and other implications of joint review in multinational research involving resource-poor countries.

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“Because It Was Hard . . .”: Some Lessons Developing a Joint IRB Between Moi University (Kenya) and Indiana University (USA)

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A proposed committee involving Moi University in Eldoret, Kenya, and Indiana University (IU) School of Medicine was cited by Barachi and colleagues as an example of “joint review/combined review” without comment. While some of this is described elsewhere (Meslin, Were, and Ayuku 2013), we suspect it may not have been available to those authors; therefore, in this commentary we offer further

explanation of our experience, which may be instructive for those contemplating collaborative ethics review and offer some further lessons we have learned.

The idea for a joint institutional review board (IRB) arose as a logical evolution of the two-decade-long IU–Kenya Partnership between Indiana and Moi universities (Tierney et al. 2013). The partnership’s mission expanded in 2001 to

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